

8 prepare the data for estimating HbA_{1c} using a predetermined sequence of
9 mathematical formulas defined as:
10 pre-process the data;
11 estimate HbA_{1c} using at least one of four predetermined formulas; and
12 validate the estimate via sample selection criteria.

1 38. A computer program product comprising a computer useable medium
2 having computer program logic for enabling at least one processor in a computer system
3 to evaluate the HbA_{1c} of a patient based on BG data collected over a first predetermined
4 duration, said computer program logic comprising:
5 preparing the data for estimating HbA_{1c} using a predetermined sequence of
6 mathematical formulas defined as:
7 pre-processing of the data,
8 estimating HbA_{1c} using at least one of four predetermined formulas, and
9 validation of the estimate via sample selection criteria.

1 39. The computer program product of claim 38, wherein said computer
2 program logic further comprises the steps of claim 11.

1 40. A method for evaluating the long term probability for severe
2 hypoglycemia (SH) and/or moderate hypoglycemia (MH) of a patient based on BG data
3 collected over a predetermined duration, said method comprising:
4 computing LBGI based on said collected BG data; and
5 estimating the number of future SH episodes using a predetermined mathematical
6 formula based on said computed LBGI.

1 41. The method of claim 40, wherein:
2 said computed LBGI is mathematically defined from a series of BG readings x_1 ,
3 $x_2 \dots x_n$ taken at time points $t_1, t_2 \dots, t_n$ as:

$$LBGI = \frac{1}{n} \sum_{i=1}^n lbgi(x_i; 2)$$

where:

$lbgi(BG; a) = 10 \cdot f(BG)^a$ if $f(BG) > 0$ and 0 otherwise,
 $a =$ about 2, representing a weighting parameter.

42. The method of claim 40, further comprising:
 defining predetermined risk categories(RCAT), each of said risk
 categories(RCAT) representing a range of values for LBGI; and
 assigning said LBGI to at least one of said risk categories(RCAT).

43. The method of claim 42, wherein said risk categories(RCAT) are defined
 as follows:
 category 1, wherein said LBGI is less than about 0.25;
 category 2, wherein said LBGI is between about 0.25 and about 0.50;
 category 3, wherein said LBGI is between about 0.50 and about 0.75;
 category 4, wherein said LBGI is between about 0.75 and about 1.0;
 category 5, wherein said LBGI is between about 1.0 and about 1.25;
 category 6, wherein said LBGI is between about 1.25 and about 1.50;
 category 7, wherein said LBGI is between about 1.5 and about 1.75;
 category 8, wherein said LBGI is between about 1.75 and about 2.0;
 category 9, wherein said LBGI is between about 2.0 and about 2.5;
 category 10, wherein said LBGI is between about 2.5 and about 3.0;
 category 11, wherein said LBGI is between about 3.0 and about 3.5;
 category 12, wherein said LBGI is between about 3.5 and about 4.25;
 category 13, wherein said LBGI is between about 4.25 and about 5.0;
 category 14, wherein said LBGI is between about 5.0 and about 6.5; and
 category 15, wherein said LBGI is above about 6.5.

44. The method of claim 42, further comprising:

2 defining a probability of incurring a select number of SH episodes respectively for
3 each of said assigned risk categories(RCAT).

1 45. The method of claim 42, further comprising:
2 defining a probability of incurring a select number of SH episodes within a next
3 first predetermined duration respectively for each of said assigned risk categories(RCAT),
4 using the formula:

5 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:

6 a = about -4.19

7 b = about 1.75

1 46. The method of claim 45, wherein said first predetermined duration is about
2 one month.

1 47. The method of claim 45, wherein said first predetermined duration ranges
2 from about 0.5 months to about 1.5 months.

1 48. The method of claim 45, wherein said first predetermined duration ranges
2 from about 0.5 months to about 3 months.

1 49. The method of claim 42, further comprising:
2 defining a probability of incurring a select number of SH episodes within a next
3 second predetermined duration respectively for each of said assigned risk
4 categories(RCAT), using the formula:

5 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:

6 a = about -3.28

7 b = about 1.50

1 50. The method of claim 49, wherein said second predetermined duration is
2 about three months.

1 51. The method of claim 49, wherein said second predetermined duration
2 ranges from about 2 months to about 4 months.

1 52. The method of claim 49, wherein said second predetermined duration
2 ranges from about 3 months to about 6 months.

1 53. The method of claim 42, further comprising:
2 defining a probability of incurring a select number of SH episodes within the next
3 third predetermined duration respectively for each of said assigned risk
4 categories(RCAT), using the formula:

5 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:

6 a = about -3.06

7 b = about 1.45.

1 54. The method of claim 53, wherein said third predetermined duration is
2 about 6 months.

1 55. The method of claim 53, wherein said third predetermined duration ranges
2 from about 5 months to about 7 months.

1 56. The method of claim 53, wherein said third predetermined duration ranges
2 from about 3 months to about 9 months.

1 57. The method of claim 42, further comprising:
2 defining a probability of incurring a select number of MH episodes within the next
3 month respectively for each of said assigned risk categories(RCAT), using the formula:

4 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:

5 a = about -1.58

6 b = about 1.05.

1 58. The method of claim 42, further comprising:
2 defining a probability of incurring a select number of MH episodes within the next
3 3 months respectively for each of said assigned risk categories(RCAT), using the
4 formula:

5 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:
6 a = about -1.37
7 b = about 1.14.

1 59. The method of claim 42, further comprising:
2 defining a probability of incurring a select number of MH episodes within the next
3 6 months respectively for each of said assigned risk categories(RCAT), using the
4 formula:

5 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:
6 a = about -1.37
7 b = about 1.35.

1 60. The method of claim 40, further comprising:
2 assigning classifications of risk for future significant hypoglycemia of the patient.

1 61. The method of claim 60, wherein said classifications are defined as
2 follows:

3 minimal risk, wherein said LBGi is less than about 1.25;
4 low risk, wherein said LBGi is between about 1.25 and about 2.50;
5 moderate risk, wherein said LBGi is between about 2.5 and about 5; and
6 high risk, wherein said LBGi is above about 5.0.

1 62. A system for evaluating the long term probability for severe hypoglycemia
2 (SH) and/or moderate hypoglycemia (MH) of a patient based on BG data collected over a
3 predetermined duration, said system comprising:

4 a database component operative to maintain a database identifying said BG data;
 5 and
 6 a processor programmed to:
 7 compute LBGI based on said collected BG data, and
 8 estimate the number of future SH episodes using a predetermined
 9 mathematical formula based on said computed LBGI.

1 63. The method of claim 62, wherein:
 2 said computed LBGI is mathematically defined from a series of BG readings x_1 ,
 3 $x_2 \dots x_n$ taken at time points t_1, t_2, \dots, t_n as:

$$4 \quad LBGI = \frac{1}{n} \sum_{i=1}^n lbgi(x_i; 2)$$

5 where:

6 $lbgi(BG; a) = 10 \cdot f(BG)^a$ if $f(BG) > 0$ and 0 otherwise,
 7 $a = \text{about } 2$, representing a weighting parameter.

1 64. The system of claim 62, further comprising:
 2 defining predetermined risk categories(RCAT), each of said risk
 3 categories(RCAT) representing a range of values for LBGI; and
 4 assigning said LBGI to at least one of said risk categories(RCAT).

1 65. The system of claim 64, wherein said risk categories (RCAT) are defined
 2 as follows:

3 category 1, wherein said LBGI is less than about 0.25;
 4 category 2, wherein said LBGI is between about 0.25 and about 0.50;
 5 category 3, wherein said LBGI is between about 0.50 and about 0.75;
 6 category 4, wherein said LBGI is between about 0.75 and about 1.0;
 7 category 5, wherein said LBGI is between about 1.0 and about 1.25;
 8 category 6, wherein said LBGI is between about 1.25 and about 1.50;
 9 category 7, wherein said LBGI is between about 1.5 and about 1.75;

10 category 8, wherein said LBGI is between about 1.75 and about 2.0;
11 category 9, wherein said LBGI is between about 2.0 and about 2.5;
12 category 10, wherein said LBGI is between about 2.5 and about 3.0
13 category 11, wherein said LBGI is between about 3.0 and about 3.5;
14 category 12, wherein said LBGI is between about 3.5 and about 4.25;
15 category 13, wherein said LBGI is between about 4.25 and about 5.0;
16 category 14, wherein said LBGI is between about 5.0 and about 6.5; and
17 category 15, wherein said LBGI is above about 6.5.

1 66. The system of claim 64, further comprising:
2 defining a probability of incurring a select number of SH episodes respectively for
3 each of said assigned risk categories (RCAT).

1 67. The system of claim 64, further comprising:
2 defining a probability of incurring a select number of SH episodes within a next
3 first predetermined duration respectively for each of said assigned risk categories(RCAT),
4 using the formula:

5 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:

6 a = about -4.19

7 b = about 1.75.

1 68. The system of claim 67, wherein said first predetermined duration is about
2 one month.

1 69. The system of claim 67, wherein said first predetermined duration ranges
2 from about 0.5 months to about 1.5 months.

1 70. The system of claim 67, wherein said first predetermined duration ranges
2 from about 0.5 months to about 3 months.

1 78. The system of claim 75, wherein said third predetermined duration ranges
2 from about 3 months to about 9 months.

1 79. The system of claim 64, further comprising:
2 defining a probability of incurring a select number of MH episodes within the next
3 month respectively for each of said assigned risk categories(RCAT), using the formula:

4 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:

5 a = about -1.58

6 b = about 1.05.

1 80. The system of claim 64, further comprising:
2 defining a probability of incurring a select number of MH episodes within the next
3 3 months respectively for each of said assigned risk categories(RCAT), using the
4 formula:

5 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:

6 a = about -1.37

7 b = about 1.14.

1 81. The system of claim 64, further comprising:
2 defining a probability of incurring a select number of MH episodes within the next
3 6 months respectively for each of said assigned risk categories(RCAT), using the
4 formula:

5 $F(x) = 1 - \exp(-a.x^b)$ for any $x > 0$ and 0 otherwise, wherein:

6 a = about -1.37

7 b = about 1.35.

1 82. The system of claim 62, further comprising:
2 assigning classifications of risk for future significant hypoglycemia of the patient.

1 83. The system of claim 82, wherein said classifications are defined as

2 follows:

- 3 minimal risk, wherein said LBGI is less than about 1.25;
- 4 low risk, wherein said LBGI is between about 1.25 and about 2.50;
- 5 moderate risk, wherein said LBGI is between about 2.5 and about 5; and
- 6 high risk, wherein said LBGI is above about 5.0.

1 84. A system for evaluating the long term probability for severe hypoglycemia
2 (SH) and/or moderate hypoglycemia (MH) of a patient based on BG data collected over a
3 predetermined duration, said system comprising:

- 4 a BG acquisition mechanism, said acquisition mechanism configured to acquire
- 5 BG data from the patient;
- 6 a database component operative to maintain a database identifying said BG data;
- 7 and
- 8 a processor programmed to:
 - 9 compute LBGI based on said collected BG data, and
 - 10 estimate the number of future SH episodes using a predetermined
 - 11 mathematical formula based on said computed LBGI.

1 85. A computer program product comprising a computer useable medium
2 having computer program logic for enabling at least one processor in a computer system
3 to evaluate the long term probability for severe hypoglycemia (SH) and/or moderate
4 hypoglycemia (MH) of a patient based on BG data collected over a predetermined
5 duration, said computer program logic comprising:

- 6 computing LBGI based on said collected BG data; and
- 7 estimating the number of future SH episodes using a predetermined mathematical
- 8 formula based on said computed LBGI.

1 86. The computer program product of claim 85, wherein said computer
2 program logic further comprises the steps of claim 42.

1 91. The method of claim 87, wherein:
 2 computing provisional LBGI based on said collected BG data, said computed provisional
 3 LBGI is mathematically defined from mathematically defined as:

$$\begin{aligned} 4 \quad & \text{LBGI}(1) = \text{RLO}(x_1) \\ 5 \quad & \text{RLO2}(1) = 0 \\ 6 \quad & \text{LBGI}(j) = ((j-1)/j) * \text{LBGI}(j-1) + (1/j) * \text{RLO}(x_j) \\ 7 \quad & \text{RLO2}(j) = ((j-1)/j) * \text{RLO2}(j-1) + (1/j) * (\text{RLO}(x_j) - \text{LBGI}(j))^2. \end{aligned}$$

1 92. The method of claim 91, wherein:
 2 computing SBGI, said computed SBGI is mathematically defined as:
 3 $\text{SBGI}(n) = \sqrt{\text{RLO2}(n)}$.

1 93. The method of claim 92, comprising qualifying or providing a warning of
 2 upcoming short term SH wherein if:

3 $(\text{LBGI}(150) \geq 2.5 \text{ and } \text{LBGI}(50) \geq (1.5 * \text{LBGI}(150) \text{ and } \text{SBGI}(50) \geq$
 4 $\text{SBGI}(150))$ then said issue of warning is qualified or provided, or
 5 $\text{RLO} \geq (\text{LBGI}(150) + 1.5 * \text{SBGI}(150))$ then said issue of warning is
 6 qualified or provided;
 7 otherwise:
 8 a warning is not necessarily qualified or provided.

1 94. The method of claim 92, comprising qualifying or providing a warning of
 2 upcoming short term SH wherein if:

3 $(\text{LBGI}(n) \geq \alpha \text{ and } \text{SBGI}(n) \geq \beta)$ then said issue of warning is qualified
 4 or provided, and/or
 5 $(\text{RLO}(n) \geq (\text{LBGI}(n) + \gamma * \text{SBGI}(n)))$ then said issue of warning is qualified
 6 or provided;
 7 otherwise:
 8 a warning is not necessarily qualified or provided, wherein α , β , and γ are

9 threshold parameters.

1 95. The method of claim 94, wherein said threshold parameters α , β , and γ are
2 defined as α = about 5, β = about 7.5, γ = about 1.5.

1 96. The method of claim 94, wherein said threshold parameters α , β , and γ are
2 defined as any combination in a, b, and/or c, or as any intermediate combination of values
3 of said parameters between the values of said parameters in a, b, and/or c below:

4 a) α = 6.4, β = 8.2, γ = 1.5, α = 5.0, β = 7.5, γ = 1.3;

5 b) α = 6.0, β = 7.5, γ = 1.5, α = 4.9, β = 7.0, γ = 1.2; and/or

6 c) α = 5.5, β = 7.5, γ = 1.5, α = 4.8, β = 7.0, γ = 1.2.

1 97. The method of claim 94, wherein said threshold parameters α , β , and γ are
2 defined as any combination in a, b, and/or c, or as any intermediate combination of values
3 of said parameters between the values of said parameters in a, b, and/or c below:

4 a). α about 6.4, β about 8.2, γ about 1.5, α about 5.0, β about 7.5, γ about 1.3;

5 b). α about 6.0, β about 7.5, γ about 1.5, α about 4.9, β about 7.0, γ about 1.2;

6 and/or

7 c). α about 5.5, β about 7.5, γ about 1.5, α about 4.8, β about 7.0, γ about 1.2.

1 98. A system for evaluating the short term probability for severe
2 hypoglycemia (SH) of a patient based on BG data collected over a predetermined
3 duration, said system comprising:

4 a database component operative to maintain a database identifying said BG data;

5 and

6 a processor programmed to:

7 compute scale values based on said collected BG data; and

8 compute the low BG risk value (RLO) for each BG data.

1 99. The system of claim 98, wherein:

2 said computed RLO(BG) is mathematically defined as:

3 $\text{Scale} = [\ln(\text{BG})]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl

4 $\text{Risk} = 22.765(\text{Scale})^2$

5 if (BG is less than about 112.5) then:

6 $\text{RLO}(\text{BG}) = \text{Risk}$, otherwise

7 $\text{RLO}(\text{BG}) = 0$.

1 100. The system of claim 98, wherein:

2 said computed RLO(BG) is mathematically defined as:

3 $\text{Scale} = [\ln(\text{BG})]^{1.026} - 1.861$, wherein BG is measured in units of mmol/l

4 $\text{Risk} = 32.184(\text{Scale})^2$

5 if (BG is \leq about 112.5) then:

6 $\text{RLO}(\text{BG}) = \text{Risk}$, otherwise

7 $\text{RLO}(\text{BG}) = 0$.

1 101. The system of claim 98, wherein:

2 computing LBGI based on said collected BG data, said computed LBGI is

3 mathematically defined from a series of BG readings x_1, x_2, \dots, x_n taken at time points $t_1, t_2,$
4 \dots, t_n as:

$$5 \quad LBGI = \frac{1}{n} \sum_{i=1}^n lbgi(x_i; 2)$$

6 where:

$$7 \quad lbgi(BG; a) = \text{RLO}(BG).$$

1 102. The system of claim 98, wherein:

2 computing provisional LBGI based on said collected BG data, said computed provisional
3 LBGI is mathematically defined from mathematically defined as:

$$4 \quad \text{LBGI}(1) = \text{RLO}(x_1)$$

$$5 \quad \text{RLO2}(1) = 0$$

$$\begin{aligned} \text{LBGI}(j) &= ((j-1)/j) * \text{LBGI}(j-1) + (1/j) * \text{RLO}(x_j) \\ \text{RLO2}(j) &= ((j-1)/j) * \text{RLO2}(j-1) + (1/j) * (\text{RLO}(x_j) - \text{LBGI}(j))^2. \end{aligned}$$

103. The system of claim 102, wherein:
 computing SBGI, said computed SBGI is mathematically defined as:

$$\text{SBGI}(n) = \sqrt{\text{RLO2}(n)}.$$

104. The system of claim 103, comprising qualifying or providing a warning of
 upcoming short term SH wherein if:

$$(\text{LBGI}(150) \geq 2.5 \text{ and } \text{LBGI}(50) \geq (1.5 * \text{LBGI}(150) \text{ and } \text{SBGI}(50) \geq$$

$$\text{SBGI}(150)) \text{ then said issue of warning is qualified or provided, or}$$

$$\text{RLO} \geq (\text{LBGI}(150) + 1.5 * \text{SBGI}(150)) \text{ then said issue of warning is}$$

 qualified or provided;
 otherwise:
 a warning is not necessarily qualified or provided.

105. The system of claim 103, comprising qualifying or providing a warning of
 upcoming short term SH wherein if:

$$(\text{LBGI}(n) \geq \alpha \text{ and } \text{SBGI}(n) \geq \beta) \text{ then said issue of warning is qualified}$$

 or provided, and/or

$$(\text{RLO}(n) \geq (\text{LBGI}(n) + \gamma * \text{SBGI}(n))) \text{ then said issue of warning is qualified}$$

 or provided;
 otherwise:
 a warning is not necessarily qualified or provided, wherein α , β , and γ are
 threshold parameters.

106. The system of claim 105, wherein said threshold parameters α , β , and γ are
 defined as $\alpha = \text{about } 5$, $\beta = \text{about } 7.5$, $\gamma = \text{about } 1.5$.

5 comprising:
6 computing scale values based on said collected BG data; and
7 computing the low BG risk value (RLO) for each BG data.

1 111. The computer program product of claim 110, wherein said computer
2 program logic further comprises the steps of claim 92.